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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,044

12/03/2004

Douglas Levinson

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EXAMINER

PETERSEN, CLARK D

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,044	<b>Applicant(s)</b> LEVINSON ET AL.	
	<b>Examiner</b> Clark D. Petersen	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 32-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Drawings***

The drawings are objected to because Figs. 6A and 6B are too dark to be understood. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, it is not clear how Applicants carry out a method of soaking cells in culture in a medium comprising supersaturated calcium oxalate. Hawley's Condensed Chemical Dictionary defines supersaturation as:

"The condition in which a solvent contains more dissolved matter (solute) than is present in a saturated solution of the same components at equivalent temperature. Such solutions may occur or can be made when a saturated solution cools gradually so that nucleating crystals do not form. They are extremely unstable and will precipitate upon addition of even one or two crystals of the solute or upon shaking or other slight agitation."

The instant specification does not give guidance as to how such a solution would be manipulated such that it would be stable enough to carry out experiments with cells. For example, it would seem from the definition of supersaturation that the cells themselves might precipitate calcium oxalate as soon as the supersaturated solution was added. Additionally, agitation as the solution was added, or in the course of the manipulation of the cells, would seem to be capable of causing precipitation.

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The specification gives guidance in Fig. 4, for example. At step 420, labeled seed crystals are "incubated and prepared". These crystals are added to cells. This is not enough information to support the claims language, which seems to indicate the cells are to be incubated with the crystals in a supersaturated calcium oxalate solution.

Figure 4 of the instant specification is described in detail from p. 53 line 30 to p. 54 line 28. These pages of the instant specification provide no guidance as to what concentration of calcium oxalate is included in the cells' medium, or how that concentration is achieved and maintained. The instant specification also contains no working examples of producing and monitoring calcium oxalate crystals in cell culture.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "*preparing* seed crystals of calcium oxalate"...."comprising at least one of a plurality of *components*"..."identifying a *component* corresponding to a change in said crystal property".

It is unclear what is meant by "preparing" or what steps should be taken in "preparing" seed crystals. It is unclear what "components" or "component" describes. The specification attempts to define "component" as a disease-causing solid, or an ingredient in the sample medium, dissolved or undissolved, that induce or inhibit crystal

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formation. However the breadth of this definition fails to make clear how a "component" is defined.

Claim 32 recites ""further comprising culturing kidney epithelial cells". It is unclear from this claim in what manner the culturing of kidney epithelial cells relates to the steps recited in claim 1, from which claim 32 depends.

Claim 33 recites that the cultured cells can be "tubule fragments". This term is not defined in the specification.

Claim 34 recites "preparing labeled calcium oxalate crystals". It is unclear what is meant by "prepared" or "labeled".

Claim 35 recites "solubilizing *washed* cells". It is unclear what is meant by "washed".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on-sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Baumann et al (Urol Res, 1990). Baumann teaches a method of studying crystallization of calcium oxalate in supersaturated solution. They add seed crystals to initiate precipitation and observe crystal growth in the presence of various inhibitors. They detect growth of crystals as a function of calcium depletion from solution (see Materials and Methods, p. 230; see Fig. 1, p. 230 as examples). Therefore the teachings of Baumann et al are deemed to anticipate instant claim 1.

Claims 1, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lieske et al (Kidney Int, 1998). Lieske et al teach a method of forming and observing calcium oxalate crystals in BSC-1 cell culture. (see Methods, p. 797 col. 1, for example). The same techniques were used for MDCK cells as well (see 798 col. 2, for example). Therefore the teachings of Lieske et al are deemed to anticipate instant claims 1, 32, and 33.

Claims 1 and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Verkoelen et al (J Urol, 1996). Verkoelen et al teach a method of studying crystal attachment to MDCK cells. They teach addition of crystals to MDCK cells in a saturated calcium oxalate solution. The crystals are prepared from a supersaturated solution containing radiolabeled oxalic acid so that upon formation calcium oxalate crystals contain  $^{14}\text{C}$ . Various polysaccharides are added with the crystals to the MDCK cells. The MDCK cells are incubated with the crystals and polysaccharides and subsequently

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washed with Buffer B. The filters containing cells are put in scintillation vials and the radioactivity is extracted using perchloric acid, reading on solubilizing the cells. The radioactivity, which corresponds to adherent crystals, is measured in a scintillation counter (see Materials and Methods, pp. 749-751). Therefore the teachings of Verkoelen et al are deemed to anticipate instant claims 1 and 32-36.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

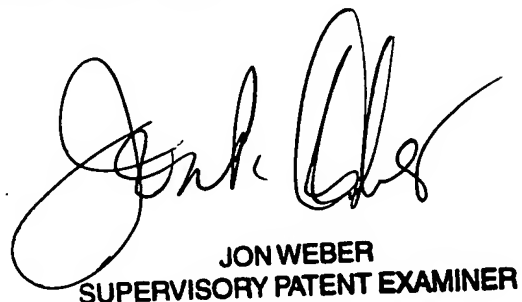
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP  
2/16/2007



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**